

# Identification of Medicinal Products (IDMP) Update July 2015



# labelnet is a community for labelling professionals

- Network, insight, and learning
- Exchange and develop best practices
  - Forums
  - Working Groups
  - Benchmark
  - Communities
- Build profile and industry voice
- Focus on member interests
- Agreement to confidentiality

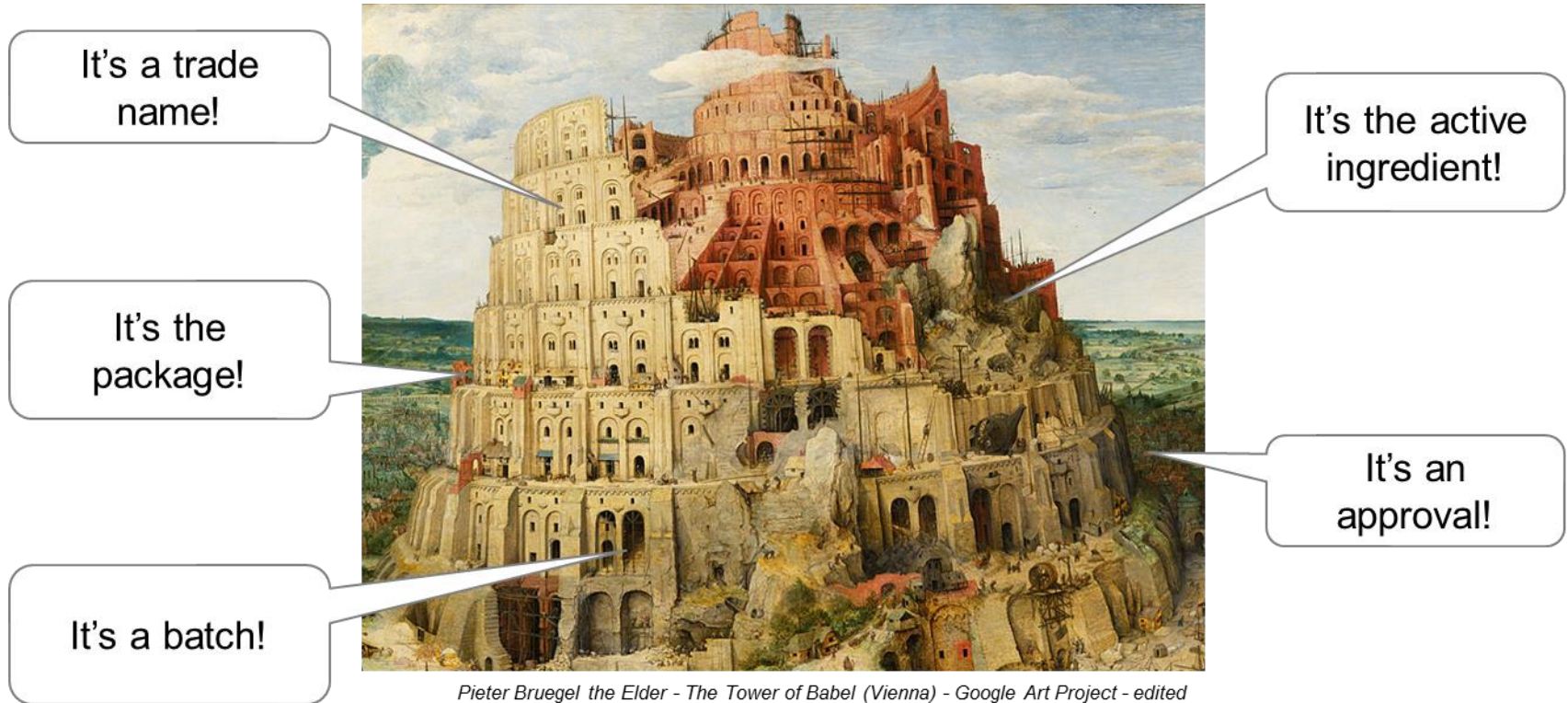


*Logos are representative only and are not for external distribution*



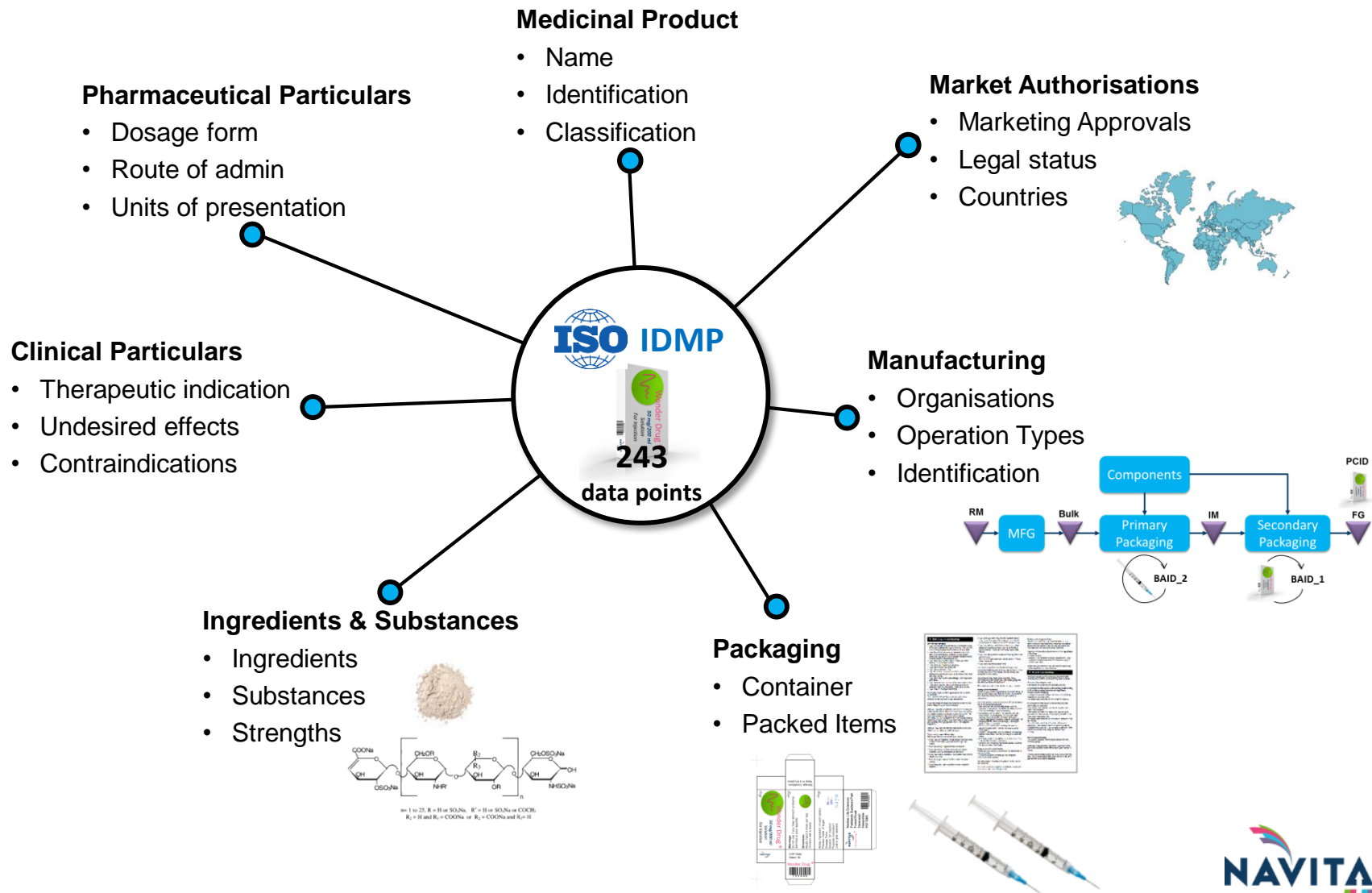
# So, what is IDMP?...

## let's start with “*What is a product?*”



**Working without a common language for products  
makes it more difficult to function with a holistic view**

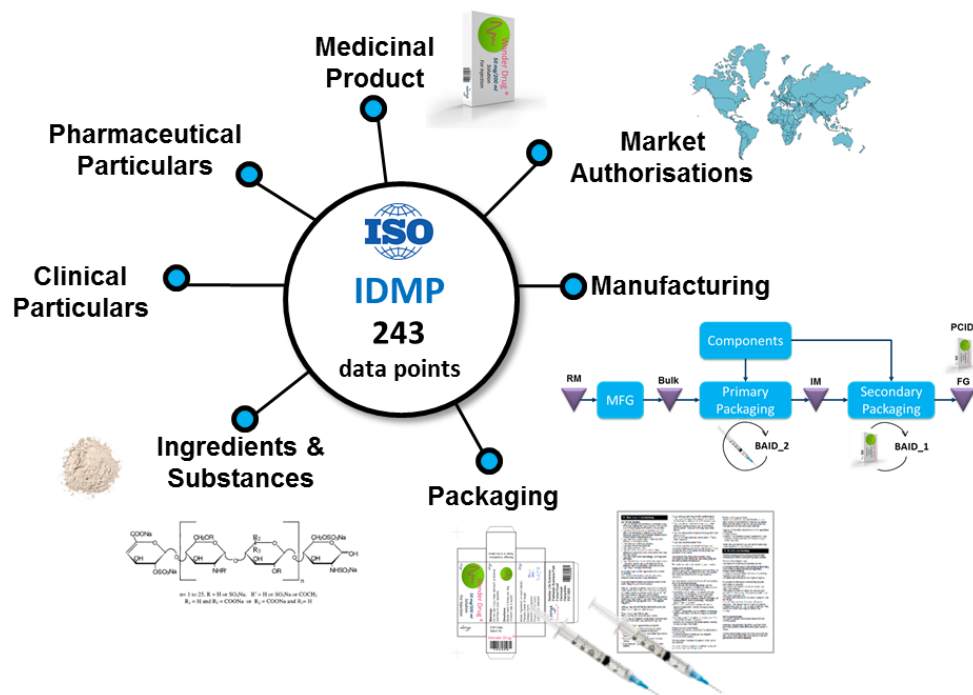
# IDMP data describes what a product is, where it is authorized, how it looks, and where its parts come from



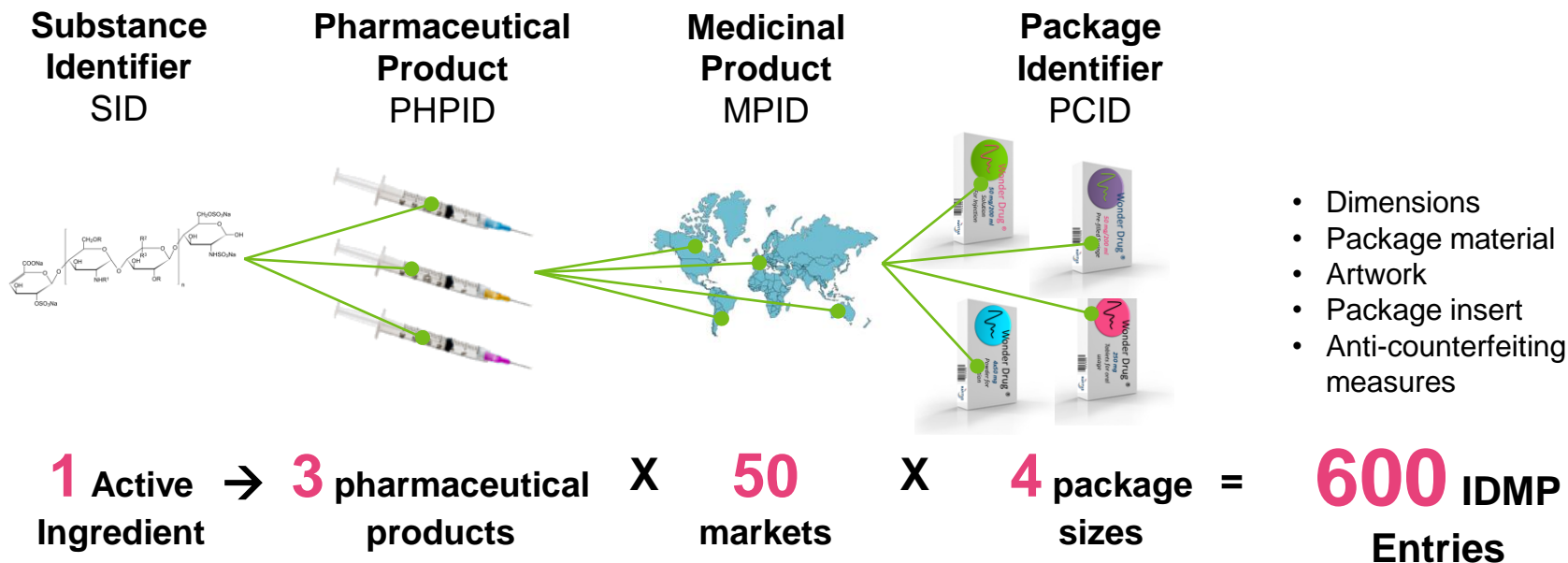
# Much of the content in IDMP has similarities to SPL

## Example Elements from SPL

- Active ingredient
- Active moiety
- Inactive ingredients
- Route of administration
- Colour
- Shape
- Indications and Usage
- Marketing Status
- Packaging
- Parts

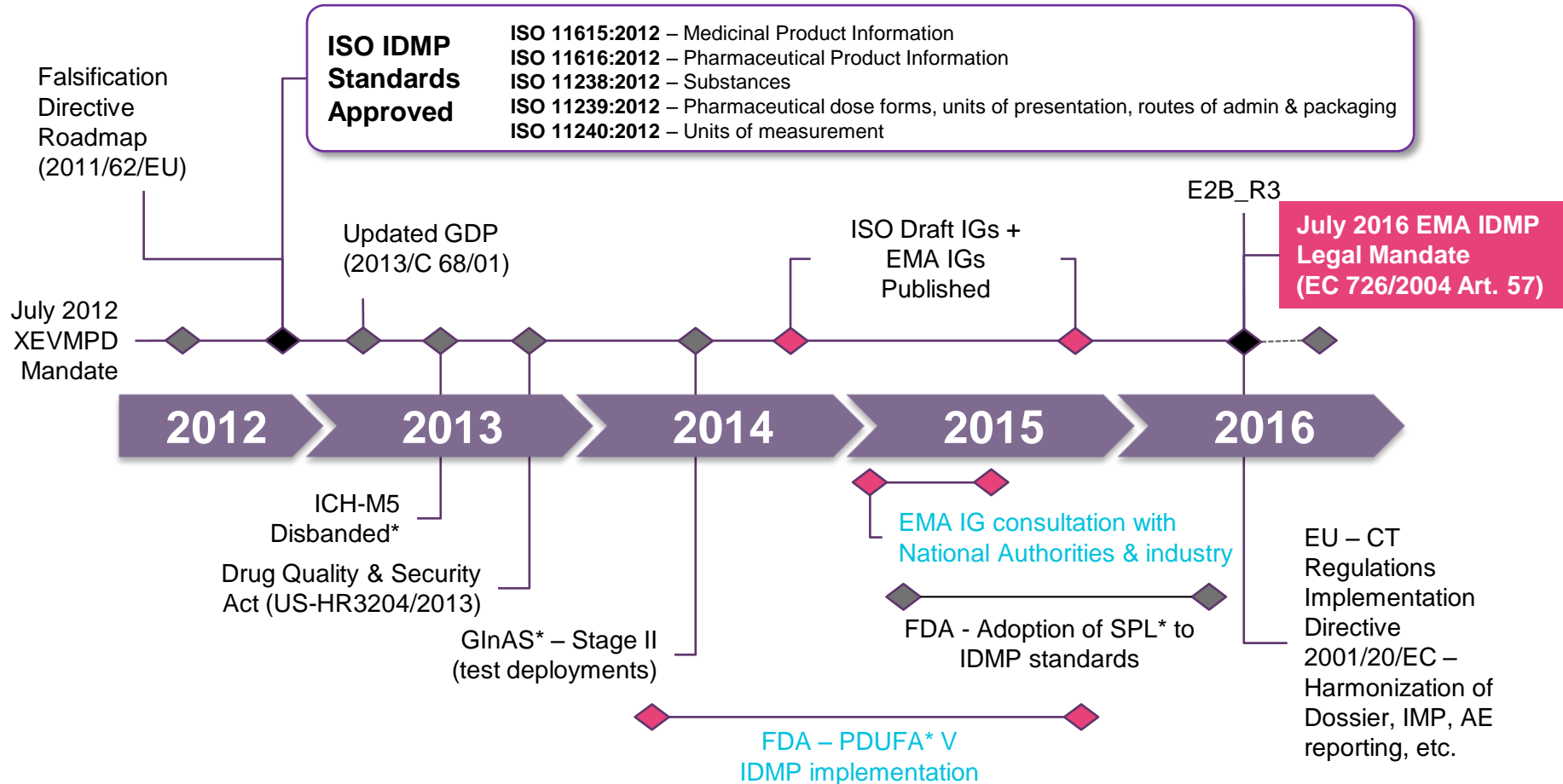


# The amount of data required for IDMP quickly multiplies when we consider its structure



- Product information is scattered across various systems and possibly various instances of the same system
- The systems will be owned by various functions in the business
- The information in the systems may not be accurate

# So far, it is the EMA July 2016 requirement which is driving this



\* SPL: Structured Product Labelling

\* GInAS: Global Ingredient Archive System, to facilitate implementation of ISO-11238

\* EMA, FDA, Switzerland, Canada continue IDMP implementation outside of ICH

\* PDUFA V – IT/Informatics Plan FY 2013 – FY 2017 (FDA)

# Latest regulatory intelligence on IDMP

## EMA

- EMA regulatory requirement in July 2016
- Implementation Guidelines not expected until early 2016
- XEVMPD to run in parallel for ~1 year
- ISO IDMP Task Force recently formed

## ○ June 23rd EMA / DIA Information Day

### Task Force Proposal

- Iterative approach extending into 2018
- First wave
  - > XEVMPD times two
  - Substance information
  - Packaging information
  - Includes development products

## Other Agencies

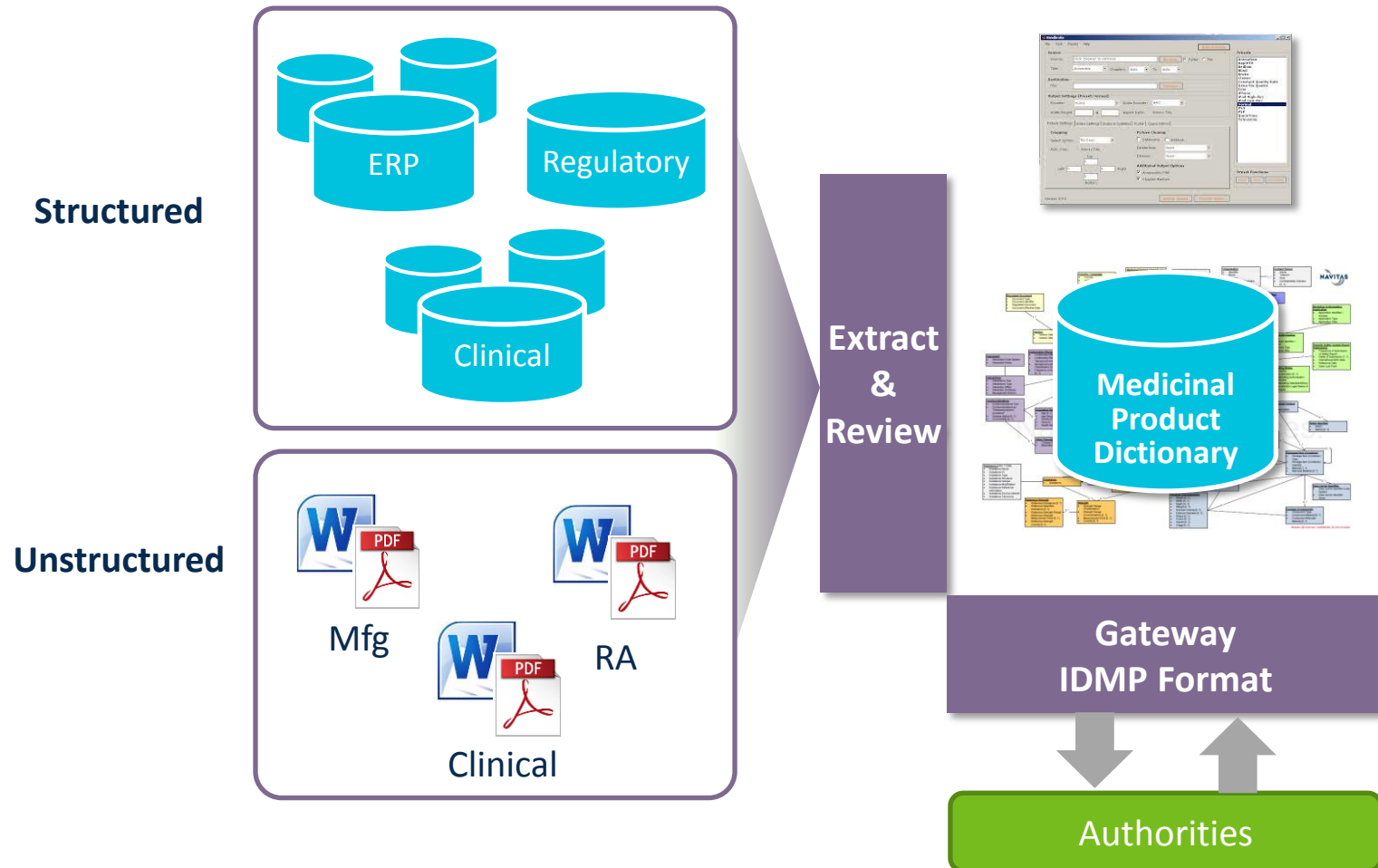
- FDA - IDEX (Vada Perkins)
- Swissmedic and HealthCanada engaged and planning
- Japan re-engaged

## Technology

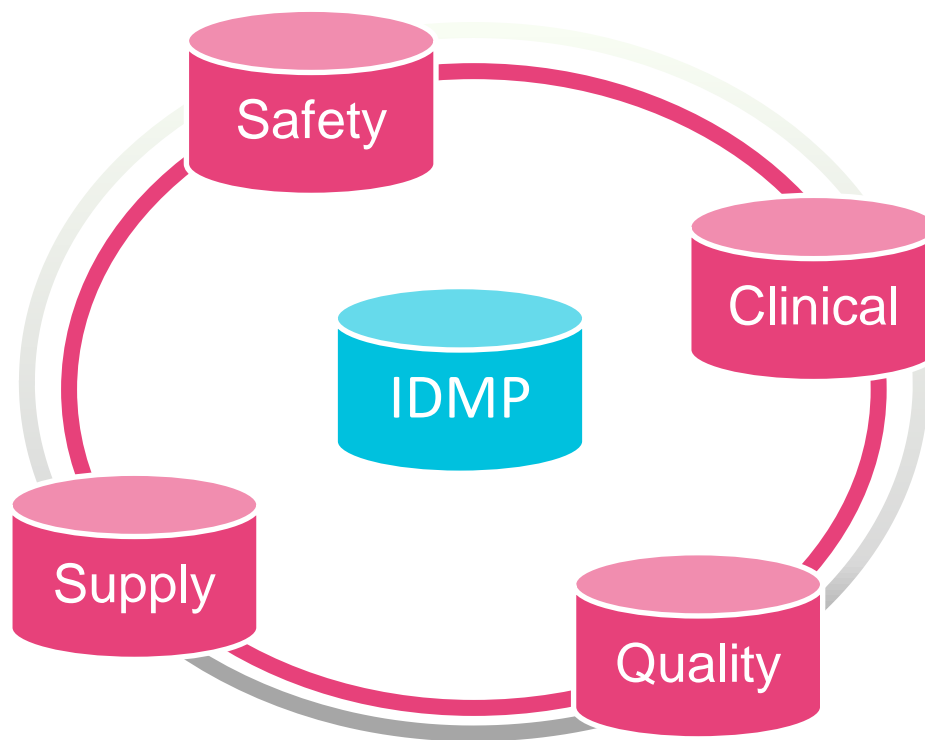
- No Regulator appears to have selected a technology yet
- EMA likely to implement solution March 2017
- Proposal at HL7 RCRIM for IDMP data to be exchanged using SPLv7
  - Ballot closed / closing soon



# Gathering the information is proving to be challenging for many companies



**The intent is that this will eventually help accelerate holistic Benefit/Risk monitoring and analysis**



# IDMP and other Collateral

<http://www.navitas.net/resources>

White Papers available for your reference:

- **A unique view of sustainable IDMP solutions**
- **IDMP Imperative – to implement compliant and efficient processes, governance and technology in line with IDMP regulations**
- Accelerate your TrackWise upgrade with Navitas
- Building a Regulatory Information Enterprise Architecture
- Social Media for pharma: the key to getting it right
- The Challenge of Regulatory Information Management



# Thank you!



Any questions, please contact

[jeffrey.ho@navitas.net](mailto:jeffrey.ho@navitas.net)

+44 07769 681 335

[denis.fung@navitas.net](mailto:denis.fung@navitas.net)

+44 07766 502 327